

118TH CONGRESS
1ST SESSION

S. _____

【To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.】

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

【To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.】

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 [“2023 Reauthorization of the Pandemic and All-Hazards
6 Preparedness Act”].

7 (b) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

2

Sec. 1. Short title; table of contents.

TITLE I—STATE AND LOCAL READINESS AND RESPONSE

- Sec. 101. Public Health Emergency Preparedness program.
- Sec. 102. Improving and enhancing participation of EMS organizations in the Hospital Preparedness Program.
- Sec. 103. Improving medical readiness and response capabilities.
- Sec. 104. Pilot program to support State medical stockpiles.
- Sec. 105. Enhancing domestic wastewater surveillance for pathogen detection.
- Sec. 106. Reauthorization of Mosquito Abatement for Safety and Health program.

TITLE II—FEDERAL PLANNING AND COORDINATION

- Sec. 201. All-Hazards Emergency Preparedness and Response.
- Sec. 202. Strategic National Stockpile and material threats.
- Sec. 203. Medical countermeasures for viral threats with pandemic potential.
- Sec. 204. Public Health Emergency Medical Countermeasures Enterprise.
- Sec. 205. Pilot program for public health data availability.

TITLE III—ADDRESSING THE NEEDS OF ALL INDIVIDUALS

- Sec. 301. Transition of certain countermeasures between compensation programs.
- Sec. 302. Accelerating injury compensation program administration and ensuring program integrity.
- Sec. 303. Review of regulations.
- Sec. 304. Supporting individuals with disabilities during emergency responses.
- Sec. 305. National advisory committees.
- Sec. 306. Research and coordination of activities concerning the long-term health effects of SARS-CoV-2 infection.

TITLE IV—STRENGTHENING BIOSECURITY

- Sec. 401. Treatment of genetic variants and synthetic products of select agents and toxins.
- Sec. 402. Establishment of no-fault reporting system.
- Sec. 403. Evaluation of the Federal Select Agent Program and related policies.
- Sec. 404. Supporting research and laboratory surge capacity.

TITLE V—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

- Sec. 501. Epidemic Intelligence Service loan repayment program.
- Sec. 502. Temporary reassignment of State and local personnel during a public health emergency.
- Sec. 503. Vaccine tracking and distribution.
- Sec. 504. Regional health care emergency preparedness and response systems.
- Sec. 505. Emergency system for advance registration of volunteer health professional.
- Sec. 506. Limited antitrust exemption.
- Sec. 507. Trauma care.
- Sec. 508. Military and civilian partnership for trauma readiness.
- Sec. 509. National Disaster Medical System.
- Sec. 510. Volunteer Medical Reserve Corps.
- Sec. 511. Epidemiology-laboratory capacity grants.

Sec. 512. Veterans Affairs.
 Sec. 513. Technical amendments.

TITLE VI—ADDITIONAL POLICIES OUTSIDE THE STAFF
 AGREEMENT FOR STAKEHOLDER FEEDBACK

Subtitle A—Chair Sanders Staff Proposal

Sec. 601. BARDA reasonable pricing requirements.
 Sec. 602. CDC reasonable pricing requirements.

Subtitle B—Ranking Member Cassidy Staff Proposal

Sec. 611. Priority review to encourage treatments for agents that present national security threats.

1 **TITLE I—STATE AND LOCAL**
 2 **READINESS AND RESPONSE**

3 **SEC. 101. PUBLIC HEALTH EMERGENCY PREPAREDNESS**
 4 **PROGRAM.**

5 Section 319C–1 of the Public Health Service Act (42
 6 U.S.C. 247d–3a) is amended—

7 (1) in subsection (b)(2)—

8 (A) in subparagraph (A)(ii), by striking
 9 “influenza” and inserting “response planning”;
 10 and

11 (B) in subparagraph (H), by inserting “,
 12 such as community-based organizations, includ-
 13 ing faith-based organizations, and other public
 14 and private entities” after “stakeholders”;

15 (2) in subsection (g)—

16 (A) in paragraph (1), in the matter pre-
 17 ceding subparagraph (A), by inserting “and the
 18 ability of each entity receiving an award under
 19 subsection (a) to respond to all-hazards

1 threats” before the period at the end of the
2 first sentence;

3 (B) in paragraph (2)—

4 (i) in the paragraph heading, by strik-
5 ing “INFLUENZA” and inserting “RE-
6 SPONSE”; and

7 (ii) in subparagraph (A)—

8 (I) by striking “to pandemic in-
9 fluenza” and inserting “to a pathogen
10 causing a pandemic, including pan-
11 demic influenza”; and

12 (II) by striking “such pandemic
13 influenza” and inserting “such pan-
14 demic response”;

15 (C) in paragraph (5)—

16 (i) in the paragraph heading, by strik-
17 ing “INFLUENZA” and inserting “PAN-
18 DEMIC RESPONSE”;

19 (ii) in the matter preceding subpara-
20 graph (A), by striking “2019” and insert-
21 ing **["2025"]**;

22 **[(iii) in clause (i), by striking “2018”**
23 **and inserting **["2024"]**; and]**

1 (iv) in subparagraph (B), by striking
2 “pandemic influenza” and inserting “a
3 pathogen causing a pandemic”; and

4 (D) in paragraph (6)—

5 (i) in subparagraph (A), in the matter
6 preceding clause (i), by striking “The
7 amounts described in this paragraph are
8 the following amounts that are payable to
9 an entity for activities described in this
10 section of section 319C–2” and inserting
11 “The Secretary shall withhold from an en-
12 tity pursuant to paragraph (5) for non-
13 compliance with the requirements of this
14 section or section 319C–2 as follows”; and

15 (ii) in subparagraph (B), by inserting
16 “with respect to the requirements of this
17 section or section 319C–2” after “para-
18 graph (5)”; and

19 (3) in subsection (h)(1)(A), by striking
20 “\$685,000,000 for each of fiscal years 2019 through
21 2023” and inserting “**【\$685,000,000】** for each of
22 fiscal years 2024 through 2028”.

1 **SEC. 102. IMPROVING AND ENHANCING PARTICIPATION OF**
2 **EMS ORGANIZATIONS IN THE HOSPITAL PRE-**
3 **PAREDNESS PROGRAM.**

4 (a) INCREASING PARTICIPATION BY EMS IN THE
5 HOSPITAL PREPAREDNESS PROGRAM.—Section 319C-2
6 of the Public Health Service Act (42 U.S.C. 247d-3b) is
7 amended—

8 (1) in subsection (b)(1)(A)—

9 (A) in clause (iii)(III), by striking “; and”
10 and inserting semicolon; and

11 (B) by striking clause (iv) and inserting
12 the following:

13 “(iv) one or more emergency medical
14 service organizations; and

15 “(v) to the extent practicable, one or
16 more emergency management organiza-
17 tions; and”;

18 (2) in subsection (g)(1)—

19 (A) by striking the heading and inserting:

20 “(1) LOCAL RESPONSE CAPABILITIES.—

21 “(A) PROGRAM COORDINATION.—”;

22 (B) by striking “extent practicable, en-
23 sure” and inserting the following: “extent prac-
24 ticable—

25 “(i) ensure”;

1 (C) by striking the period and inserting “;
2 and”; and

3 (D) by adding at the end the following:

4 “(ii) seek to increase participation of
5 underrepresented eligible entities described
6 in subsection (b)(1)(A), such as emergency
7 medical services organizations and health
8 care facilities in underserved areas.”.

9 (b) PREFERENCES.—Section 319C–2(d)(1)(A)(iii) of
10 the Public Health Service Act (42 U.S.C. 247d–
11 3b(d)(1)(A)(iii)) is amended by striking “subsection
12 (b)(1)(A)(ii)” and inserting “clauses (ii) and (iv) of sub-
13 section (b)(1)(A)”.

14 **SEC. 103. IMPROVING MEDICAL READINESS AND RESPONSE**
15 **CAPABILITIES.**

16 The Public Health Service Act is amended—

17 (1) in section 319C–2 (42 U.S.C. 247d–3b)—

18 (A) in subsection (b)(2)—

19 (i) in subparagraph (A), by striking
20 “and” at the end;

21 (ii) in subparagraph (B), by striking
22 the period and inserting “; and”; and

23 (iii) by inserting at the end the fol-
24 lowing:

1 “(C) designate a lead entity, which shall not be
2 a component of an eligible entity that is responsible
3 for carrying out regulatory activities related to
4 health care facilities within the applicable State or
5 political subdivision of a State, to administer such
6 award and support coordination between entities de-
7 scribed in this subsection.”;

8 (B) in subsection (g)(1), as amended by
9 section 102(a)(2), by adding at the end the fol-
10 lowing:

11 “(B) REGIONAL OPERATIONS.—An eligible
12 entity **【shall】** establish and maintain, or lever-
13 age an existing, capability to enable coordina-
14 tion of regional medical operations, which may
15 include systems to facilitate information sharing
16 and coordination, within a coalition described
17 under subsection (b)(1)(A) and, as appropriate,
18 between multiple coalitions that are in close ge-
19 ographic proximity to each other.”; and

20 (C) in subsection (j)(1)(A), by striking
21 “\$385,000,000 for each of fiscal years 2019
22 through 2023” and inserting “**【\$385,000,000】**
23 for each of fiscal years 2024 through 2028”;
24 and

1 (2) in section 2802(b) (42 U.S.C. 300hh–
2 1(b))—

3 (A) in paragraph (3)(C), by inserting “and
4 current capacity of facilities within such sys-
5 tems, as applicable” before the period;

6 (B) in paragraph (5), by inserting “appli-
7 cable federally-funded activities and” after “(in-
8 cluding”;

9 (C) in paragraph (8)—

10 (i) in subparagraph (A), by inserting
11 “public health and medical” before “activi-
12 ties”;

13 (ii) in subparagraph (B), by striking
14 “familiarity with” and inserting “under-
15 standing of, and coordination between,”.

16 **SEC. 104. PILOT PROGRAM TO SUPPORT STATE MEDICAL**
17 **STOCKPILES.**

18 (a) IN GENERAL.—Section 319F–2(i) of the Public
19 Health Service Act (42 U.S.C. 247d–6b(i)) is amended—

20 (1) in paragraph (2)(B)(i)—

21 (A) in subclause (I), by striking “and
22 2024” and inserting “through 2025”; and

23 (B) in subclause (II), by striking “2025”
24 and inserting “2026”;

25 (2) in paragraph (4)—

1 (A) in subparagraph (G), by striking “;
2 and” at the end and inserting a semicolon;

3 (B) by redesignating subparagraph (H) as
4 subparagraph (I);

5 (C) by inserting after subparagraph (G)
6 the following:

7 “(H) facilitate the sharing of best practices
8 between States within a consortia of States in
9 receipt of funding related to establishing and
10 maintaining a stockpile of medical products;
11 and”;

12 (D) in subparagraph (I), as so redesign-
13 ated, by striking “State efforts” and inserting
14 “State or regional efforts”;

15 (3) by redesignating paragraphs (5) through
16 (9) as paragraphs (6) through (10), respectively;
17 and

18 “(5) COORDINATION.—An entity in receipt of
19 an award under paragraph (1), in carrying out the
20 activities under this subsection, shall coordinate with
21 appropriate health care entities, health officials, and
22 emergency management officials within the jurisdic-
23 tion of such State or States.”; and

24 (4) in paragraph (10), as so redesignated, by
25 striking “\$3,500,000,000 for each of fiscal years

1 2023 and 2024” and inserting “[such sums] as
2 may be necessary for each of fiscal years 2024
3 through 2028”.

4 (b) GAO REPORT.—Section 2409(b) of the PRE-
5 VENT Pandemics Act (Public Law 117–328) is amend-
6 ed—

7 (1) in paragraph (2), by striking “; and” and
8 inserting a semicolon;

9 (2) in paragraph (3), by striking the period and
10 inserting “; and”; and

11 (3) by adding at the end the following:

12 “(4) the impact of any regional stockpiling ap-
13 proaches carried out under such subsection (i)(1) of
14 section 319F–2 of the Public Health Service Act (42
15 U.S.C. 247d–6b).”.

16 **SEC. 105. ENHANCING DOMESTIC WASTEWATER SURVEIL-**
17 **LANCE FOR PATHOGEN DETECTION.**

18 (a) IN GENERAL.—Subtitle C of title XXVIII of the
19 Public Health Service Act (42 U.S.C. 300hh–31 et seq.)
20 is amended by adding at the end the following:

21 **“SEC. 2827. WASTEWATER SURVEILLANCE FOR PATHOGEN**
22 **DETECTION.**

23 “(a) WASTEWATER SURVEILLANCE SYSTEM.—The
24 Secretary, acting through the Director of the Centers for
25 Disease Control and Prevention and in coordination with

1 other Federal departments and agencies, shall award
2 grants, contracts, or cooperative agreements to eligible en-
3 tities to establish, maintain, or improve activities related
4 to the detection and monitoring of infectious diseases
5 through wastewater for public health emergency prepared-
6 ness and response purposes.

7 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
8 an award under this section, an entity shall—

9 “(1) be a State, Tribal, or local health depart-
10 ment, or a partnership between such a health de-
11 partment and other public and private entities; and

12 “(2) submit to the Secretary an application at
13 such time, in such manner, and containing such in-
14 formation as the Secretary may reasonably require,
15 which shall include—

16 “(A) a description of activities proposed to
17 be carried out pursuant to an award under sub-
18 section (a);

19 “(B) factors such entity proposes to use to
20 select wastewater sampling sites;

21 “(C) a plan for responding, as appropriate,
22 to findings from such wastewater sampling,
23 consistent with applicable plans developed by
24 such entity pursuant to section 319C-1;

1 “(D) a plan to sustain such wastewater
2 surveillance activities described in such applica-
3 tion following the conclusion of the award pe-
4 riod; and

5 “(E) any additional information the Sec-
6 retary may require.

7 “(c) CONSIDERATION.—In making awards under sub-
8 section (a), the Secretary may give priority to eligible enti-
9 ties that have submitted an application that—

10 “(1) details plans to provide **[public]** access to
11 data generated through such wastewater surveillance
12 activities in a manner that enables comparison to
13 such data generated by other recipients of an award
14 under subsection (a); and

15 “(2) provides an assessment of community
16 needs related to ongoing infectious disease moni-
17 toring, including burden of infectious diseases that
18 can be detected in wastewater and availability of
19 other forms of infectious disease surveillance.

20 “(d) USE OF FUNDS.—An eligible entity shall use
21 amounts awarded under this section to—

22 “(1) establish, or enhance existing, capacity and
23 capabilities to conduct wastewater sampling and re-
24 lated analysis;

1 “(2) conduct wastewater surveillance, as appro-
2 priate, at individual facilities, institutions, and loca-
3 tions in rural areas, in which there is an increased
4 risk of infectious disease outbreaks and wastewater
5 is [not treated through the relevant local utility of
6 the jurisdiction]; and

7 “(3) implement projects that use evidence-based
8 or promising practices to conduct wastewater sur-
9 veillance activities.

10 “(e) PARTNERSHIPS.—In carrying out activities
11 under this section, eligible entities shall identify opportuni-
12 ties to partner with other public or private entities to le-
13 verage relevant capabilities maintained by such entities,
14 as appropriate and consistent with this section.

15 “(f) TECHNICAL ASSISTANCE.—The Secretary, in
16 consultation with the heads of other applicable Federal
17 agencies and departments, as appropriate, shall provide
18 technical assistance to recipients of awards under this sec-
19 tion to facilitate the planning, development, and imple-
20 mentation of activities described in subsection (d).

21 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
22 carry out this section, there is authorized to be appro-
23 priated [such sums as may be necessary] for each of fiscal
24 years 2024 through 2028.”.

25 (b) WASTEWATER SURVEILLANCE RESEARCH.—

1 (1) IN GENERAL.—The Secretary of Health and
2 Human Services (in this subsection referred to as
3 the “Secretary”) shall continue to conduct or sup-
4 port research on the use of wastewater surveillance
5 to detect and monitor emerging infectious diseases,
6 which may include—

7 (A) research to improve the efficiency of
8 wastewater sample collection and analysis and
9 increase the sensitivity and specificity of waste-
10 water testing methods; and

11 (B) implementation and development of
12 evidence-based practices to facilitate the esti-
13 mation of population-level data within a com-
14 munity.

15 (2) NON-DUPLICATION OF EFFORT.—The Sec-
16 retary shall ensure that activities carried out under
17 this subsection do not unnecessarily duplicate efforts
18 of other agencies and offices within the Department
19 of Health and Human Services related to wastewater
20 surveillance.

21 **SEC. 106. REAUTHORIZATION OF MOSQUITO ABATEMENT**
22 **FOR SAFETY AND HEALTH PROGRAM.**

23 Section 317S of the Public Health Service Act (42
24 U.S.C. 247b–21) is amended—

1 (1) in subsection (a)(3)(A), by striking “sub-
2 section (b)(3)” and inserting “subsection (b)(4)”;

3 (2) in subsection (b)—

4 (A) by redesignating paragraphs (3)
5 through (6) as paragraphs (4) through (7), re-
6 spectively; and

7 (B) by inserting after paragraph (2) the
8 following:

9 “(3) CONSIDERATIONS.—The Secretary may
10 consider the use of innovative and novel technology
11 for mosquito prevention and control in making
12 grants under paragraph (1).”;

13 (3) by amending subsection (d) to read as fol-
14 lows:

15 “(d) USES OF FUNDS.—

16 “(1) TECHNICAL ASSISTANCE.—Amounts ap-
17 propriated under subsection (f) may be used by the
18 Secretary to provide training and technical assist-
19 ance with respect to the planning, development, and
20 operation of assessments and plans under subsection
21 (a) and control programs under subsection (b). The
22 Secretary may provide such training and technical
23 assistance directly or through awards of grants or
24 contracts to public and private entities.

1 “(B) DEVELOPMENT OF REQUIRE-
2 MENTS.—Lead the development and approval,
3 and, on a routine basis, the review and update,
4 of requirements for such countermeasures and
5 products, including related capabilities, to in-
6 form the advanced research, development, pro-
7 curement, and replenishment decisions of the
8 Department of Health and Human Services.”;

9 (B) in paragraph (4)—

10 (i) in subparagraph (F)—

11 (I) in the matter preceding clause
12 (i), by striking “and in consultation
13 with the Secretary of Homeland Secu-
14 rity,”; and

15 (II) in clause (i), by inserting
16 “enhance” after “capabilities and”;
17 and

18 (ii) in subparagraph (G)—

19 (I) in clause (i), by striking
20 “based on” and inserting “based on—
21 ”;

22 (II) in clause (ii), by striking “;
23 and” at the end and inserting a semi-
24 colon;

1 (III) in clause (iii), by striking
2 the period and inserting “; and”;

3 (IV) by adding at the end the fol-
4 lowing:

5 “(iv) that include, as appropriate, par-
6 ticipation by relevant industry, academia,
7 professional societies, and other stake-
8 holders.”;

9 (iii) in subparagraph (H)—

10 (I) by inserting “and the Direc-
11 tor of the Office of Pandemic Pre-
12 paredness and Response” after “Secu-
13 rity Affairs”; and

14 (II) by inserting “and medical
15 product and supply capacity planning
16 pursuant to subparagraph (J), includ-
17 ing discussion of any relevant identi-
18 fied supply chain vulnerabilities” be-
19 fore the period at the end;

20 (iv) in subparagraph (I), by inserting
21 “the Director of the Office of Pandemic
22 Preparedness and Response Policy,” after
23 “Security Affairs,”; and

24 (v) in subparagraph (J)(i), in the
25 matter preceding subclause (I), by insert-

1 ing “, including needs for active pharma-
2 ceutical ingredients, key starting materials,
3 and other critical components of such
4 products and supplies,” after “supply
5 needs”; and

6 (C) in paragraph (7)—

7 (i) in the matter preceding subpara-
8 graph (A), by inserting “and the require-
9 ments developed pursuant to paragraph
10 (3)(B)” after “subsection (d)”;

11 (ii) by redesignating subparagraphs
12 (E) and (F) as subparagraphs (F) and
13 (G), respectively; and

14 (iii) by inserting after subparagraph
15 (D) the following:

16 “(E) include a professional judgment of
17 anticipated budget needs for each future fiscal
18 year accounted for in such plan to account for
19 the full range of anticipated medical counter-
20 measure needs and life-cycle costs to address
21 such priorities and requirements;”;

22 (2) in subsection (d)—

23 (A) by amending paragraph (1) to read as
24 follows:

1 “(1) IN GENERAL.—Not later than March 15,
2 2020, and biennially thereafter, the Assistant Sec-
3 retary for Preparedness and Response shall develop
4 and submit to the Committee on Health, Education,
5 Labor, and Pensions of the Senate and the Com-
6 mittee on Energy and Commerce of the House of
7 Representatives a coordinated strategy for medical
8 countermeasures to address chemical, biological, ra-
9 diological, and nuclear threats, informed by the re-
10 quirements developed pursuant to subsection
11 (b)(3)(B). Not later than **[180 days]** after the sub-
12 mission of such strategy to such committees, the As-
13 sistant Secretary for Preparedness and Response
14 shall submit an accompanying implementation plan
15 to such committees. In developing such a strategy
16 and plan, the Assistant Secretary for Preparedness
17 and Response shall consult with the Public Health
18 Emergency Medical Countermeasures Enterprise es-
19 tablished under section 2811–1.”; and

20 (B) in paragraph (2), in the matter pre-
21 ceding subparagraph (A), by inserting “strategy
22 and” before “plan”; and

23 (3) in subsection (f)—

24 (A) in paragraph (1), in the matter pre-
25 ceding subparagraph (A), by inserting “, includ-

1 has an increased likelihood to be-
2 come resistant to, or evade, such
3 countermeasure relative to other
4 available medical counter-
5 measures;” and

6 (B) in paragraph (3)—

7 (i) in subparagraph (B), by striking
8 “are followed, regularly reviewed, and up-
9 dated with respect to such stockpile” and
10 inserting “with respect to such stockpile
11 are followed, regularly reviewed, and up-
12 dated to reflect best practices”;

13 (ii) by redesignating subparagraphs
14 (H) through (K) as subparagraphs (I)
15 through (L), respectively; and

16 (iii) by inserting after subparagraph
17 (G) the following:

18 “(H) utilize tools to enable the timely and
19 accurate tracking, including the location and
20 geographic distribution, of the contents of the
21 stockpile throughout the deployment of such
22 contents;” and

23 (2) in subsection (c)(2)(C)—

24 (A) by striking “promptly”; and

1 (B) by inserting “, not later than **【60**
2 **days】** after such determination”;

3 (3) in subsection (g)(1), by striking “
4 \$7,100,000,000 for the period of fiscal years 2019
5 through 2028” and inserting “**【\$7,100,000,000】** for
6 the period of fiscal years 2024 through 2033”.

7 **SEC. 203. MEDICAL COUNTERMEASURES FOR VIRAL**
8 **THREATS WITH PANDEMIC POTENTIAL.**

9 (a) **IN GENERAL.**—Section 319L(c)(4) of the Public
10 Health Service Act (42 U.S.C. 247d–7e(c)(4)) is amend-
11 ed—

12 (1) in subparagraph (D), by amending clause
13 (iii) to read as follows:

14 “(iii) conduct research to promote
15 strategic initiatives, such as—

16 “(I) rapid diagnostics;

17 “(II) broad spectrum
18 antimicrobials;

19 “(III) medical countermeasures
20 for virus families that have significant
21 potential to cause a pandemic, includ-
22 ing such countermeasures that take
23 either pathogen-specific or broad spec-
24 trum approaches; and

1 “(IV) technologies to improve the
2 production and use of medical coun-
3 termeasures, which may include vac-
4 cine-manufacturing technologies, dose-
5 sparing technologies, efficacy-increas-
6 ing technologies, platform tech-
7 nologies, technologies to administer
8 countermeasures, and technologies to
9 improve storage and transportation of
10 countermeasures.”; and

11 (2) in subparagraph (F)(ii), by inserting “pri-
12 ority virus families, and other viral pathogens with
13 a significant potential to cause a pandemic,” after
14 “pandemic influenza,”.

15 **SEC. 204. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
16 **TERMEASURES ENTERPRISE.**

17 Section 2811–1(c) of the Public Health Service Act
18 (42 U.S.C. 300hh–10a(c)) is amended—

19 (1) in paragraph (2), by striking “, as appro-
20 priate”; and

21 (2) by adding at the end the following:

22 “(3) INFORMATION SHARING.—The Secretary
23 shall, as appropriate and in a manner that does not
24 compromise national security, share information re-
25 lated to recommendations made and strategies devel-

1 oped under subparagraphs (A) and (C) of paragraph
2 (1) with relevant stakeholders, including industry
3 and State, local, and Tribal public health depart-
4 ments.”.

5 **SEC. 205. PILOT PROGRAM FOR PUBLIC HEALTH DATA**
6 **AVAILABILITY.**

7 (a) SITUATIONAL AWARENESS SYSTEM.—Section
8 319D of the Public Health Service Act (42 U.S.C. 247d–
9 4) is amended—

10 (1) in subsection (c)—

11 (A) in paragraph (1), by inserting “, and
12 facilitate the aggregation of relevant public
13 health data across the Department of Health
14 and Human Services” after “extent prac-
15 ticable”; and

16 (B) in paragraph (2)—

17 (i) in subparagraph (A)—

18 (I) by striking “among agencies”
19 and inserting “among, and direct
20 communication between, agencies”;

21 (II) by inserting “the sharing of
22 information from applicable public
23 health data systems,” after “Tech-
24 nology);”; and

- 1 (III) by striking “; and” at the
2 end and inserting a semicolon; and
3 (ii) in subparagraph (B), by striking
4 the period at the end and inserting “;
5 and”; and
6 (iii) by adding at the end the fol-
7 lowing:
8 “(C) facilitate bidirectional communication
9 between agencies and offices of the Department
10 of Health and Human Services and State, local,
11 and Tribal public health officials.”; and
12 (2) in subsection (d)—
13 (A) in paragraph (1)—
14 (i) by striking “, the Secretary may”
15 and inserting “and support the near real-
16 time public availability of data pursuant to
17 section 319D–2, the Secretary **【shall】** es-
18 tablish a pilot program to”; and
19 (ii) by striking “, in collaboration with
20 appropriate” and inserting “. Such States
21 or consortia of States shall carry out such
22 activities in collaboration with appropriate
23 stakeholders, such as”;

1 (B) in paragraph (2)(A), by inserting
2 “pursuant to paragraph (3)” after “may re-
3 quire”;

4 (C) by striking paragraph (6);

5 (D) by redesignating paragraphs (3)
6 through (5) as paragraphs (4) through (6), re-
7 spectively;

8 (E) by inserting after paragraph (2) the
9 following:

10 “(3) DATA GUIDANCE.—For purposes of this
11 subsection, the Secretary shall develop guidance on
12 data elements to be reported to the Secretary per-
13 taining to potentially catastrophic infectious disease
14 outbreaks, in such form and manner and at such
15 timing and frequency as determined by the Sec-
16 retary. When developing the guidance under this
17 subsection, the Secretary shall—

18 “(A) adopt and update, as necessary and
19 consistent with applicable requirements of sub-
20 section (b)(3) and section 2823, uniform stand-
21 ards for applicable entities to report data ele-
22 ments; and

23 “(B) ensure the data elements reported
24 under this subsection and made publicly avail-
25 able pursuant to section 319D–2 are made

1 available consistent with applicable Federal and
2 State privacy law, at a minimum.”; and

3 (F) in paragraph (4), as so redesignated—

4 (i) in subparagraph (A), by striking
5 “emergencies;” and inserting “emer-
6 gencies, including such diseases rec-
7 ommended by the National Public Health
8 Data Board established under section
9 319D–2; and”;

10 (ii) in subparagraph (B), by striking
11 “; and” and inserting a period; and

12 (iii) by striking subparagraph (C).

13 (b) DATA SELECTION AND ACCESS.—Title III of the
14 Public Health Service Act (42 U.S.C. 241 et seq.) is
15 amended by inserting after section 319D–1 the following:

16 **“SEC. 319D–2. PUBLIC HEALTH DATA PILOT PROGRAM.**

17 “(a) IN GENERAL.—The Secretary shall—

18 “(1) establish and maintain a near real-time,
19 open source, public-facing, and publicly available
20 website to provide deidentified, aggregated data on
21 potentially catastrophic disease outbreaks, in accord-
22 ance with subsection (b); and

23 “(2) collect the data elements pertaining to
24 such diseases recommended pursuant to subsection

1 (b)(1)(B), using existing processes or any new pro-
2 cesses established pursuant to section 319D(d).

3 “(b) NATIONAL PUBLIC HEALTH DATA BOARD.—

4 “(1) IN GENERAL.—The Secretary shall estab-
5 lish a National Public Health Data Board to advise,
6 and make recommendations to the Secretary with re-
7 spect to—

8 “(A) **the implementation of data and in-**
9 **formation sharing under section 310B**]; and

10 “(B) potentially catastrophic infectious dis-
11 eases appropriate for inclusion in the public
12 health situational awareness system pilot pro-
13 gram established pursuant to section 319D(d)
14 and the website established under subsection
15 (a)(1).

16 “(2) MEMBERSHIP.—The Board established
17 under paragraph (1) shall consist of the following
18 members:

19 “(A) FEDERAL MEMBERS.—The following
20 Federal members:

21 “(i) The Secretary of Health and
22 Human Services.

23 “(ii) The Secretary of Defense.

24 “(iii) The Secretary of Veterans Af-
25 fairs.

1 “(ii) individuals with such other spe-
2 cific expertise as the Secretary determines
3 appropriate.

4 “(c) SUNSET.—This section shall cease to have force
5 or effect on September 30, 2028.”.

6 **TITLE III—ADDRESSING THE**
7 **NEEDS OF ALL INDIVIDUALS**

8 **SEC. 301. TRANSITION OF CERTAIN COUNTERMEASURES**
9 **BETWEEN COMPENSATION PROGRAMS.**

10 (a) TREATMENT OF INELIGIBILITY OF CERTAIN RE-
11 QUESTS RELATED TO COVID–19 COUNTERMEASURES.—

12 (1) REQUESTS INITIALLY SUBMITTED UNDER
13 CICP.—

14 (A) IN GENERAL.—In the case of a request
15 for compensation submitted under section
16 319F–4(b)(4) of the Public Health Service Act
17 (42 U.S.C. 247d–6e(b)(4)) for an injury or
18 death related to a COVID–19 vaccine that the
19 Secretary determines to be ineligible for the
20 program pursuant to subparagraph (B) of such
21 section 319F–4(b)(4), as added by subsection
22 (b)(1), the Secretary shall, not later than 30
23 days after such determination, notify the indi-
24 vidual submitting the request of such deter-
25 mination.

1 (B) SUBMISSION OF PETITION.—An indi-
2 vidual who receives a notification described in
3 subparagraph (A) shall be eligible to submit a
4 petition to the United States Court of Federal
5 Claims under section 2111 of the Public Health
6 Service Act (42 U.S.C. 300aa–11) with respect
7 to the same injury claimed in the request sub-
8 mitted under section 319F–4(b)(4) of such Act
9 (42 U.S.C. 247d–6e(b)(4)), provided that such
10 petition is submitted not later than the later
11 of—

12 (i) 1 year after receiving such notifi-
13 cation under subparagraph (A); or

14 (ii) the last date on which the indi-
15 vidual otherwise would be eligible to sub-
16 mit a petition relating to such injury, as
17 specified in section 2116 of the Public
18 Health Service Act (42 U.S.C. 300aa–16).

19 (2) REQUESTS INITIALLY SUBMITTED UNDER
20 VICP.—

21 (A) IN GENERAL.—If a special master de-
22 termines that—

23 (i) a petition submitted under section
24 2111 of the Public Health Service Act (42
25 U.S.C. 300aa–11) related to a COVID–19

1 vaccine is ineligible for the National Vac-
2 cine Injury Compensation Program under
3 subtitle 2 of title XXI of the Public Health
4 Service Act (42 U.S.C. 300aa–10 et seq.)
5 because it relates to a vaccine administered
6 at a time when the vaccine was not in-
7 cluded in the Vaccine Injury Table under
8 section 2114 and the petitioner is not eligi-
9 ble for compensation pursuant to section
10 2116(b) of such Act (42 U.S.C. 300aa–
11 16); and

12 (ii) the vaccine was administered
13 when it was a covered countermeasure sub-
14 ject to a declaration under section 319F–
15 3(b) of such Act (42 U.S.C. 247d–6d(b)),
16 the special master shall, not later than 30 days
17 after such determination, notify the petitioner
18 of such determination.

19 (B) SUBMISSION OF REQUEST.—An indi-
20 vidual who receives a notification described in
21 subparagraph (A) shall be eligible to submit a
22 request for compensation under section 319F–
23 4(b) of the Public Health Service Act (42
24 U.S.C. 247d–6e) with respect to the same in-

1 jury claimed in the petition submitted under
2 section 2111 of such Act—

3 (i) not later than 1 year after receiv-
4 ing such notification; or

5 (ii) in the case that the notification is
6 issued after judicial review of the petition
7 under subsection (e) or (f) of section 2112
8 of such Act (42 U.S.C. 300aa–12), not
9 later than 1 year after the decision of the
10 United States Court of Federal Claim or
11 the mandate is issued by the United States
12 Court of Appeals for the Federal Circuit
13 pursuant to such subsection (e) or (f).

14 (b) CHANGES TO CERTAIN PROGRAMS.—

15 (1) CICP.—Section 319F–4(b)(4) of the Public
16 Health Service Act (42 U.S.C. 247d–6e(b)(4)) is
17 amended—

18 (A) by striking “Except as provided” and
19 inserting the following:

20 “(A) IN GENERAL.—Except as provided”;
21 and

22 (B) by adding at the end the following:

23 “(B) EXCLUSION OF INJURIES CAUSED BY
24 VACCINES ON THE VACCINE INJURY TABLE.—

25 Notwithstanding any other provision of this sec-

1 tion, no individual may be eligible for com-
2 pensation under this section with respect to a
3 covered injury caused by a vaccine that, at the
4 time it was administered, was included in the
5 Vaccine Injury Table under section 2114.”; and

6 (C) in subsection (d)(3)—

7 (i) by striking “This section” and in-
8 serting the following:

9 “(A) IN GENERAL.—This section”; and

10 (ii) by adding at the end the fol-
11 lowing:

12 “(B) EXHAUSTION OF REMEDIES.—A cov-
13 ered individual shall not be considered to have
14 exhausted remedies as described in paragraph
15 (1), nor be eligible to seek remedy under section
16 319F–3(d), unless such individual has provided
17 to the Secretary all supporting documentation
18 necessary to facilitate the determinations re-
19 quired under subsection (b)(4).”.

20 (2) VICP.—Title XXI of the Public Health
21 Service Act (42 U.S.C. 300aa–1 et seq.) is amend-
22 ed—

23 (A) in section 2111(a)(2)(A) (42 U.S.C.
24 300aa–11(a)(2)(A)), in the matter preceding
25 clause (i), by inserting “containing the informa-

1 tion required under subsection (c)” after “un-
2 less a petition”;

3 (B) in section 2112(d) (42 U.S.C. 300aa-
4 12(d))—

5 (i) by adding at the end of paragraph
6 (1) the following: “Such designation shall
7 not occur until the petitioner has filed all
8 materials required under paragraphs (2)
9 and (3) of section 2111(c).”; and

10 (ii) in paragraph (3)(A)(ii), by strik-
11 ing “the petition was filed” and inserting
12 “on which the chief special master makes
13 the designation pursuant to paragraph
14 (1)”;

15 (C) in section 2114(e) (42 U.S.C. 300aa-
16 14(e))—

17 (i) in paragraph (2), in the matter
18 preceding subparagraph (A), by striking
19 “2 years” and inserting “6 months”; and

20 (ii) by adding at the end the fol-
21 lowing:

22 【“(4) LICENSURE REQUIREMENT.—Notwith-
23 standing paragraphs (2) and (3), the Secretary may
24 not revise the Vaccine Injury Table to include a vac-
25 cine for which the Centers for Disease Control and

1 Prevention has issued a recommendation for routine
2 use in children or pregnant women until at least one
3 application for such vaccine has been approved
4 under section 351.”; and】

5 (D) in section 2116(b) (42 U.S.C. 300aa-
6 16(b))—

7 (i) in the matter preceding paragraph
8 (1), by striking “except that no compensa-
9 tion may be provided” and inserting “ex-
10 cept that no petition may be filed”;

11 (ii) in paragraph (1)—

12 (I) by striking “death” and in-
13 serting “injury or death”; and

14 (II) by striking “, or” and insert-
15 ing “;”; and

16 (iii) by striking paragraph (2) and in-
17 serting the following:

18 “(2) the vaccine was administered at a time
19 when the vaccine was a covered countermeasure sub-
20 ject to a declaration under section 319F-3(b); or

21 “(3) any request for compensation for the same
22 vaccine-related injury or death is pending, or has
23 been resolved, under the program under section
24 319F-4.”.

1 **SEC. 302. ACCELERATING INJURY COMPENSATION PRO-**
2 **GRAM ADMINISTRATION AND ENSURING PRO-**
3 **GRAM INTEGRITY.**

4 (a) NATIONAL VACCINE INJURY COMPENSATION
5 PROGRAM.—

6 **[(1) IN GENERAL.—Section 2112(c) of the**
7 **Public Health Service Act (42 U.S.C. 300aa12(c)) is**
8 **amended—]**

9 **[(A) in paragraph (1), by striking “not**
10 **more than 8 special masters” and inserting**
11 **“not fewer than 10 special masters”; and]**

12 **[(B) in paragraph (4)—]**

13 **[(i) by striking “a term of 4 years”**
14 **and inserting “an initial term of 4**
15 **years”];]**

16 **[(ii) by striking the second and third**
17 **sentences; and]**

18 **[(iii) by adding at the end the fol-**
19 **lowing: “An individual appointed as special**
20 **master may be reappointed to serve one or**
21 **more additional terms of up to 8 years**
22 **each, pursuant to paragraph (1), and sub-**
23 **ject to termination under paragraphs (2)**
24 **and (3).”.]**

1 (2) PETITIONS FOR COMPENSATION.—Section
2 2111(a)(2)(A)(i) of the Public Health Service Act
3 (42 U.S.C. 300aa–11(a)(2)(A)(i)) is amended—

4 (A) in subclause (I), by striking “, and”
5 and inserting a semicolon;

6 (B) in subclause (II)—

7 (i) by moving the margin 2 ems to the
8 right; and

9 (ii) by striking “, or” and inserting “;
10 and”; and

11 (C) by adding at the end the following:

12 “(III) the judgment described in subclause
13 (I) does not result from a petitioner’s motion to
14 dismiss the case; or”.

15 (3) COMPENSATION.—Section 2115(e)(1) of the
16 Public Health Service Act (42 U.S.C. 300aa–
17 15(e)(1)) is amended by adding at the end of the
18 flush text at the end the following: “When making
19 a determination of good faith under this paragraph,
20 the special master or court may consider whether
21 the petitioner demonstrated an intention to obtain
22 compensation on such petition.”.

23 (b) COUNTERMEASURES INJURY COMPENSATION
24 PROGRAM.—Section 319F–4 of the Public Health Service
25 Act (42 U.S.C. 247d–6e) is amended—

1 (1) in subsection (b)(4), as amended by section
2 301(b), by adding at the end the following:

3 “(C) TIMING.—

4 “(i) IN GENERAL.—Each determina-
5 tion made by the Secretary under this
6 paragraph shall be issued as expeditiously
7 as practicable but not later than 240 days,
8 exclusive of suspended time, after the date
9 the petition was filed.

10 “(ii) REQUESTS FOR RECONSIDER-
11 ATION.—Applications to request reconsid-
12 eration of a determination in accordance
13 with section 262(f)(1) shall be made within
14 60 days of notification of the determina-
15 tion. The Secretary shall complete such re-
16 consideration as expeditiously as prac-
17 ticable but not later than 90 days, exclu-
18 sive of suspended time, after the date on
19 which the reconsideration was requested.”;

20 (2) in subsection (d)—

21 (A) in paragraph (1) by striking “240
22 days” and inserting “420 days, exclusive of sus-
23 pended time,”; and

24 (B) by adding at the end the following:

1 “(6) FAILURE TO RESPOND.—If an individual
2 who submits a request for benefits under subsection
3 (a) fails to respond to subsequent requests for infor-
4 mation or action, resulting in suspended time of over
5 240 continuous days or an aggregate period of over
6 420 days, the request shall be withdrawn and the in-
7 dividual shall not be considered as having exhausted
8 available remedies for purposes of paragraph (1).
9 The Secretary shall make no fewer than 3 attempts
10 to contact the individual prior to a withdrawal, with
11 not fewer than 60 days between each such at-
12 tempt.”; and

13 (3) in subsection (e) by adding at the end the
14 following:

15 “(6) SUSPENDED TIME.—The term ‘suspended
16 time’ means time during consideration of a request
17 for compensation under subsection (b)(4) during
18 which the Secretary is awaiting further information
19 or documentation from the requesting individual, fol-
20 lowing notification of the individual by the Secretary
21 that such information or documentation is required
22 to proceed with determination of eligibility and com-
23 pensation or payment.”.

24 **[(c) *Amendments to Compensation Provided through***
25 ***CICP.*]**

1 **SEC. 303. REVIEW OF REGULATIONS.**

2 Not later than 120 days after the date of enactment
3 of this Act, the Secretary of Health and Human Services
4 shall update, as needed for purposes of carrying out the
5 amendments made by this Act, regulations governing ad-
6 ministration of the National Vaccine Injury Compensation
7 Program under subtitle 2 of title XXI of the Public Health
8 Service Act (42 U.S.C. 300aa–10 et seq.) and under the
9 Countermeasures Injury Compensation Program under
10 section 319F–4 of the Public Health Service Act (42
11 U.S.C. 247d–6e).

12 **SEC. 304. SUPPORTING INDIVIDUALS WITH DISABILITIES**
13 **DURING EMERGENCY RESPONSES.**

14 (a) **TECHNICAL ASSISTANCE CENTERS ON AT-RISK**
15 **INDIVIDUALS AND DISASTERS.—**

16 (1) **IN GENERAL.—**The Secretary of Health and
17 Human Services (referred to in this section as the
18 “Secretary”) may, through grants, contracts, or co-
19 operative agreements to eligible entities, establish
20 more than one research, training, and technical as-
21 sistance centers to provide appropriate information,
22 training, and technical assistance to States, local-
23 ities, Tribes, and other applicable entities related to
24 addressing the unique needs and considerations of
25 at-risk individuals, as defined in section 2802(b)(4)
26 of the Public Health Service Act (42 U.S.C. 300hh–

1 1(b)(4)), in the event of a public health emergency
2 declared by the Secretary pursuant to section 319 of
3 the Public Health Service Act (42 U.S.C. 247d).

4 (2) RESPONSIBILITIES OF THE CENTERS.—The
5 centers established under paragraph (1) shall con-
6 duct activities for the purpose of—

7 (A) developing, identifying, evaluating, and
8 disseminating evidence-based or evidence-in-
9 formed strategies to improve health and other
10 related outcomes for at-risk individuals related
11 to public health emergencies, including by ad-
12 dressing such unique needs and considerations
13 in carrying out public health and medical activi-
14 ties to prepare for, respond to, and recover
15 from, such public health emergencies; and

16 (B) assisting applicable entities in the im-
17 plementation of such evidence-based strategies,
18 including through sub-grants, contracts, or co-
19 operative agreements.

20 (3) PRIORITY.—In awarding grants for activi-
21 ties described in this subsection, the Secretary shall
22 give priority to eligible entities with demonstrated
23 expertise in, and ability to carry out, the activities
24 described in paragraph (2).

1 (4) CONSULTATION.—In carrying out activities
2 under paragraph (2), the centers established under
3 paragraph (1) shall take into consideration relevant
4 findings and recommendations of, and, as appro-
5 priate, consult with, the National Advisory Com-
6 mittee on Individuals with Disabilities and Disasters
7 established under section 2811C of the Public
8 Health Service Act (42 U.S.C. 300hh–10d).

9 (5) REPORTS.—Not later than 2 years after the
10 date of enactment of this Act and every 2 years
11 thereafter, the Secretary shall submit to the Com-
12 mittee on Health, Education, Labor, and Pensions
13 of the Senate and the Committee on Energy and
14 Commerce of the House of Representatives a report
15 describing the activities carried out under this sub-
16 section during the preceding 2 fiscal years.

17 (6) SUNSET.—This subsection shall cease to
18 have force or effect on September 30, 2028.

19 (b) CRISIS STANDARDS OF CARE.—Not later than 2
20 years after the date of enactment of this Act, the Sec-
21 retary, acting through the Director of the Office for Civil
22 Rights of the Department of Health and Human Services,
23 shall issue guidance to States and localities on the develop-
24 ment or modification of State and local crisis standards
25 of care for use during the response to a public health

1 emergency declared [by the governor of a State or] by
2 the Secretary under section 319 of the Public Health Serv-
3 ice Act (42 U.S.C. 247d), or a major disaster or emer-
4 gency declared by the President under section 401 or 501,
5 respectively, of the Robert T. Stafford Disaster Relief and
6 Emergency Assistance Act (42 U.S.C. 5170, 5191) to en-
7 sure that such standards of care are consistent with the
8 nondiscrimination requirements of [section 504 of the Re-
9 habilitation Act of 1973 (29 U.S.C. 794), title II of the
10 Americans with Disabilities Act of 1990 (42 U.S.C. 12131
11 et seq.), and the Age Discrimination Act of 1975 (42
12 U.S.C. 6101 et seq.)].

13 **SEC. 305. NATIONAL ADVISORY COMMITTEES.**

14 (a) NATIONAL ADVISORY COMMITTEE ON CHILDREN
15 AND DISASTERS.—Section 2811A of the Public Health
16 Service Act (42 U.S.C. 300hh–10b) is amended—

17 (1) in subsection (c)—

18 (A) by striking “may provide advice” and
19 inserting the following: “may provide—
20 “(1) advice”;

21 (B) by striking the period and inserting “;
22 and”;

23 (C) by adding at the end the following:

24 “(2) recommendations to the Director of the
25 Office of Pandemic Preparedness and Response Pol-

1 icy and to Congress with respect to the public health
2 and emergency preparedness needs of children.”;
3 and

4 (2) in subsection (g), by striking “2023” and
5 inserting “2028”.

6 (b) NATIONAL ADVISORY COMMITTEE ON SENIORS
7 AND DISASTERS.—Section 2811B of the Public Health
8 Service Act (42 U.S.C. 300hh–10c) is amended—

9 (1) in subsection (c)—

10 (A) by striking “may provide advice” and
11 inserting the following: “may provide—
12 “(1) advice”;

13 (B) by striking the period and inserting “;
14 and”;

15 (C) by adding at the end the following:

16 “(2) recommendations to the Director of the
17 Office of Pandemic Preparedness and Response Pol-
18 icy and to Congress with respect to the public health
19 and emergency preparedness needs of seniors.”;

20 (2) in subsection (d)—

21 (A) in paragraph (1), by striking “17
22 members” and inserting “25 members”; and

23 (B) in paragraph (2)—

24 (i) in subparagraph (J), by striking
25 “2” and inserting “3”;

1 (ii) in subparagraph (K), by striking
2 “2” and inserting “3”;

3 (iii) by redesignating subparagraphs
4 (K) through (L) as subparagraphs (L)
5 through (M), respectively; and

6 (iv) by inserting after subparagraph
7 (J) the following:

8 “(K) At least 2 non-Federal health care
9 professionals with expertise in gerontology.”;

10 and

11 (3) by amending subsection (g) to read as fol-
12 lows:

13 “(g) SUNSET.—The Advisory Committee shall termi-
14 nate on September 30, 2028.”.

15 (c) NATIONAL ADVISORY COMMITTEE ON INDIVID-
16 UALS WITH DISABILITIES AND DISASTERS.—Section
17 2811C of the Public Health Service Act (42 U.S.C.
18 300hh–10d) is amended—

19 (1) by redesignating subsections (c) through (g)
20 as subsections (d) through (h), respectively;

21 (2) by inserting after subsection (b) the fol-
22 lowing:

23 “(c) ADDITIONAL DUTIES.—The Advisory Committee
24 may provide—

1 “(1) advice and recommendations to the Sec-
2 retary and to Congress with respect to individuals
3 with disabilities and the medical and public health
4 grants and cooperative agreements as applicable to
5 preparedness and response activities under this title
6 and title III; and

7 “(2) recommendations to the Director of the
8 Office of Pandemic Preparedness and Response Pol-
9 icy and to Congress with respect to the public health
10 and emergency preparedness needs of individuals
11 with disabilities.”;

12 (3) in subsection (d), as so redesignated—

13 (A) in paragraph (1), by striking “17
14 members” and inserting “25 members”;

15 (B) in paragraph (2)—

16 (i) by striking subparagraphs (K)
17 through (M); and

18 (ii) by inserting after subparagraph
19 (J) the following:

20 “(K) 15 non-Federal members (at least
21 **[2]** of whom shall be individuals with disabili-
22 ties) from diverse backgrounds, including the
23 following:

24 “(i) One representative from each of
25 the following:

1 “(I) A nongovernmental organi-
2 zation that provides disaster prepared-
3 ness and response services.

4 “(II) A community-based organi-
5 zation that represents individuals with
6 multiple types of disabilities.

7 “(III) A State-based organization
8 that represents individuals with mul-
9 tiple types of disabilities.

10 “(IV) A national organization
11 that represents individuals with mul-
12 tiple types of disabilities.

13 “(V) A national organization that
14 represents older adults.

15 “(VI) An organization that pro-
16 vides relevant housing services, includ-
17 ing during the response to, and recov-
18 ery from, disasters.

19 “(VII) An organization that rep-
20 resents disabled veterans.

21 “(ii) Four individuals with geographi-
22 cally diverse expertise in emergency man-
23 agement.

24 “(iii) Two non-Federal health care
25 professionals with expertise in disability ac-

1 cessibility before, during, and after disas-
2 ters, medical and mass care disaster plan-
3 ning, preparedness, response, or recovery.

4 “(iv) Two non-Federal health care
5 professionals with expertise in disability ac-
6 cessibility before, during, and after disas-
7 ters, medical and mass care disaster plan-
8 ning, preparedness, response, or recov-
9 ery.”; and

10 (C) by adding at the end the following:

11 “(3) CONSIDERATION.—In appointing members,
12 including the Chair, to the Committee under this
13 subsection, the Secretary **【may】** give consideration
14 to disability status.”; and

15 (4) by amending subsection (h), as so redesign-
16 ated, to read as follows:

17 “(h) SUNSET.—The Advisory Committee shall termi-
18 nate on September 30, 2028.”.

19 **SEC. 306. RESEARCH AND COORDINATION OF ACTIVITIES**
20 **CONCERNING THE LONG-TERM HEALTH EF-**
21 **FFECTS OF SARS-COV-2 INFECTION.**

22 (a) IN GENERAL.—The Secretary of Health and
23 Human Services (referred to in this section as the “Sec-
24 retary”) shall, as appropriate—

1 (1) coordinate activities among relevant Federal
2 departments and agencies with respect to addressing
3 the long-term health effects of SARS-CoV-2 infec-
4 tion, which may include conditions that arise as a
5 result of such infection;

6 (2) continue to conduct or support basic, clin-
7 ical, epidemiological, behavioral, and translational
8 research and public health surveillance related to the
9 pathogenesis, prevention, diagnosis, and treatment
10 of the long-term health effects of SARS-CoV-2 in-
11 fection, which may include conditions and any ef-
12 fects on cognition and neural structure and function
13 that arise as a result of such infection; and

14 (3) consistent with the findings of studies and
15 research under paragraph (1), in consultation with
16 health professional associations, scientific and med-
17 ical researchers, and other relevant experts, develop
18 and inform recommendations, guidance, and edu-
19 cational materials on the long-term effects of SARS-
20 CoV-2 infection, which may include conditions that
21 arise as a result of such infection, and provide such
22 recommendations, guidance, and educational mate-
23 rials to health care providers and the general public.

24 (b) CONSIDERATIONS.—In conducting or supporting
25 research under this section, the Secretary shall consider

1 the diversity of research participants or cohorts to ensure
2 inclusion of a broad range of participants, as applicable
3 and appropriate.

4 (c) ADDITIONAL ACTIVITIES.—The Secretary may—

5 (1) acting through the Director of the Agency
6 for Healthcare Research and Quality, conduct or
7 support research related to—

8 (A) the improvement of health care deliv-
9 ery for individuals experiencing long-term
10 health effects of SARS-CoV-2, which may in-
11 clude conditions that arise as a result of such
12 infection;

13 (B) the identification of any trends associ-
14 ated with differences in diagnosis and treat-
15 ment of the long-term health effects of SARS-
16 CoV-2 infection and related conditions; and

17 (C) the development or identification of
18 tools and strategies to help health care entities
19 and providers care for such populations, which
20 may include addressing any differences identi-
21 fied pursuant to subparagraph (B);

22 (2) publicly disseminate the results of such re-
23 search; and

24 (3) establish a primary care technical assistance
25 initiative to convene primary care providers and or-

1 organizations, which may include support for con-
2 tinuing training and education for such providers, as
3 applicable and appropriate, in order to collect and
4 disseminate best practices related to the care of indi-
5 viduals with long-term health effects of SARS-CoV-
6 2 infection, which may include conditions that arise
7 as a result of such infection.

8 (d) ANNUAL REPORTS.—Not later than 1 year after
9 the date of enactment of this Act, and annually thereafter
10 for the next 4 years, the Secretary shall prepare and sub-
11 mit a report to the Committee on Health, Education,
12 Labor, and Pensions of the Senate and the Committee on
13 Energy and Commerce of the House of Representatives
14 regarding an overview of the research conducted or sup-
15 ported under this section and any relevant findings. Such
16 reports may include information about how the research
17 and relevant findings under this section relate to other re-
18 search efforts supported by other public or private entities.

19 (e) PUBLIC AVAILABILITY OF INFORMATION.—In
20 making information or reports publicly available under
21 this section, the Secretary shall take into consideration the
22 delivery of such information in a manner that takes into
23 account the range of communication needs of the intended
24 recipients, including at-risk individuals.

1 **TITLE IV—STRENGTHENING**
2 **BIOSECURITY**

3 **SEC. 401. TREATMENT OF GENETIC VARIANTS AND SYN-**
4 **THETIC PRODUCTS OF SELECT AGENTS AND**
5 **TOXINS.**

6 Section 351A(a)(1) of the Public Health Service Act
7 (42 U.S.C. 262a(a)(1)) is amended by adding at the end
8 the following:

9 “(C) INCLUSIONS.—

10 “(i) IN GENERAL.—For purposes of
11 the list under this paragraph, the following
12 shall be considered to be a biological agent
13 or toxin included on the list:

14 “(I) Any biological agent that in-
15 corporates nucleic acids coding for a
16 virulence factor from a listed agent or
17 toxin.

18 “(II) Any biological agent or
19 toxin that is genetically homologous to
20 a listed agent or toxin with respect to
21 nucleotides coding for virulence fac-
22 tors or toxicity.

23 “(III) Any biological agent or
24 toxin that is synthetically derived with

1 virulence or toxicity characteristics of
2 a listed agent or toxin.

3 “(IV) Any nucleic acid that en-
4 codes for components contributing to
5 pathogenicity, transmissibility, or tox-
6 icity of a listed agent or toxin.

7 “(ii) EXEMPTIONS.—The Secretary
8 may exempt from inclusion on the list
9 under this paragraph any biological agent,
10 toxin, or nucleic acid described in clause
11 (i), if such agent, toxin, or nucleic acid
12 does not meet the criteria under subpara-
13 graph (B).”.

14 **SEC. 402. ESTABLISHMENT OF NO-FAULT REPORTING SYS-**
15 **TEM.**

16 Title III of the Public Health Service Act is amended
17 by inserting after section 351A (42 U.S.C. 262a) the fol-
18 lowing:

19 **“SEC. 351B. NO-FAULT REPORTING SYSTEM.**

20 “(a) DEFINITIONS.—In this section:

21 “(1) The term ‘listed agents and toxins’ has the
22 meaning given the term in section 351A(l).

23 “(2) The term ‘reporting system’ means the re-
24 porting system established under subsection (b)(1).

25 “(b) ESTABLISHMENT.—

1 “(1) IN GENERAL.—Not later than 2 years
2 after the date of enactment of the 2023 Reauthor-
3 ization of the Pandemic and All-Hazards Prepared-
4 ness Act, the Secretary shall establish a confidential,
5 anonymous, voluntary, no-fault reporting system re-
6 lated to accidents, near-accidents, or other safety in-
7 cidents involving biological agents and toxins, in
8 order to support continuous improvement and shar-
9 ing of lessons learned related to such incidents.

10 “(2) AVAILABILITY.—The ability to submit re-
11 ports on a voluntary basis to the reporting system
12 shall be made available to individuals affiliated with
13 laboratories located in the United States, or at fed-
14 erally-funded entities outside the United States, that
15 conduct research involving biological agents and tox-
16 ins.

17 “(3) DATA.—Not later than 1 year after the
18 date of enactment of the 2023 Reauthorization of
19 the Pandemic and All-Hazards Preparedness Act,
20 the Secretary shall publish [a notice in the Federal
21 Register on/details and] plans for the reporting sys-
22 tem, including—

23 “(A) data elements that will be included in
24 the submission of reports;

1 “(B) procedures and processes for the sub-
2 mission of reports;

3 “(C) criteria for incidents that may be re-
4 ported to such system; and

5 “(D) procedures for privacy and
6 anonymization.

7 “(4) **PROTOTYPING AND TESTING.**—The Sec-
8 retary shall test and prototype the reporting system
9 for not less than 1 year before finalizing the report-
10 ing system.

11 “(5) **EXTERNAL FEEDBACK.**—The Secretary
12 shall seek feedback on development of the reporting
13 system from external stakeholders, including prior to
14 publication of the information under paragraph (3)
15 and prior to introduction of prototypes and finaliza-
16 tion of such system under paragraph (4).

17 “(c) **FOIA.**—

18 “(1) **IN GENERAL.**—Information submitted to,
19 or derived from, the reporting system shall be ex-
20 empt from disclosure under section 552 of title 5,
21 United States Code.

22 “(2) **APPLICABILITY.**—For purposes of para-
23 graph (1), this section shall be considered a statute
24 described in section 552(b)(3)(B) of title 5, United
25 States Code.

1 “(d) PROHIBITION ON USE AS EVIDENCE.—Informa-
2 tion submitted to, or derived from, the reporting system
3 shall not be used in any Federal or State enforcement ac-
4 tion or criminal prosecution.

5 “(e) PRIVACY; DISCIPLINARY ACTION FOR UNAU-
6 THORIZED DISCLOSURE.—An individual or entity that
7 submits information to the reporting system under sub-
8 section (b) shall not be required to provide their name.

9 “(f) RELATIONSHIP TO BSAT REPORTING SYS-
10 TEM.—The voluntary reporting system established under
11 this section shall supplement, and not supplant, the man-
12 datory reporting requirements applicable to the misuse of
13 listed agents and toxins.”.

14 **SEC. 403. EVALUATION OF THE FEDERAL SELECT AGENT**
15 **PROGRAM AND RELATED POLICIES.**

16 (a) IN GENERAL.—Not later than 3 years after the
17 date of enactment of this Act, the National Science Advi-
18 sory Board for Biosecurity (referred to in this section as
19 the “Board”) established pursuant to section 404O of the
20 Public Health Service Act (42 U.S.C. 283r) shall evaluate
21 the effectiveness of the Federal Select Agent Program (re-
22 ferred to in this section as the “Program”) in mitigating
23 risks to the United States population with respect to bio-
24 logical threats and make recommendations to the Presi-
25 dent related to the modernization of the Program, includ-

1 ing to address scientific advancements and integration of
2 the Program and other related Federal policies and frame-
3 works for biosafety and biosecurity.

4 (b) FRAMEWORK.—

5 (1) IN GENERAL.—The recommendations devel-
6 oped under subsection (a) shall include a proposed
7 framework for an integrated approach to the over-
8 sight of biological research that raises significant
9 biosafety and biosecurity concerns, which may in-
10 clude proposals to harmonize relevant Federal poli-
11 cies such as the following:

12 (A) The Federal Select Agent Program.

13 (B) Federal policies relating to dual-use
14 research of concern.

15 (C) Federal policies related to federally-
16 funded research involving enhanced pathogens
17 of pandemic potential.

18 (D) The Biosafety in Microbiological and
19 Biomedical Laboratories Manual of the Depart-
20 ment of Health and Human Services.

21 (E) The Guidelines for Research Involving
22 Recombinant or Synthetic Nucleic Acid Mol-
23 ecules of the National Institutes of Health.

24 (2) REQUIREMENTS FOR FRAMEWORK.—The
25 framework proposed under paragraph (1) shall—

1 (A) be developed in consultation with
2 stakeholders and experts from institutions of
3 higher education, industry, and other govern-
4 ment agencies; and

5 (B) make recommendations related to miti-
6 gating any identified risks associated with exist-
7 ing gaps in oversight of such research, which
8 may include research that does not receive Fed-
9 eral funding, taking into consideration any na-
10 tional security concerns, the potential benefits
11 of such research, considerations related to the
12 research community, transparency, and public
13 availability of information, and international re-
14 search collaboration.

15 (c) REORGANIZATION.—In carrying out this section,
16 the Board may make recommendations related to the clar-
17 ification of the authorities and responsibilities of relevant
18 Federal departments and agencies and any necessary reor-
19 ganization of such authorities and responsibilities among
20 such departments and agencies.

21 (d) REPORT.—Not later than 1 year after the
22 issuance of recommendations under subsection (a), the
23 President shall submit to the Committee on Health, Edu-
24 cation, Labor, and Pensions of the Senate and the Com-
25 mittee on Energy and Commerce of the House of Rep-

1 representatives, and, as applicable, other appropriate commit-
2 tees of Congress, a report that describes plans to imple-
3 ment such recommendations, including the identification
4 of—

- 5 (1) any barriers to implementation; and
- 6 (2) any areas in which the President disagrees
7 with the findings or recommendations of the Board.

8 **SEC. 404. SUPPORTING RESEARCH AND LABORATORY**
9 **SURGE CAPACITY.**

10 (a) IN GENERAL.—The Secretary of Health and
11 Human Services (referred to in this section as the “Sec-
12 retary”) shall make awards to establish or maintain, as
13 applicable, not fewer than 12 regional biocontainment lab-
14 oratories, for purposes of—

- 15 (1) conducting biomedical research to support
16 preparedness for, and rapid response to, biological
17 agents, including emerging infectious diseases;
- 18 (2) ensuring the availability of surge capacity
19 for purposes of responding to such biological agents;
- 20 (3) supporting information-sharing between,
21 and the dissemination of findings to, researchers and
22 other relevant individuals to facilitate collaboration
23 between industry and academia; and
- 24 (4) providing, as appropriate and applicable,
25 technical assistance and training to researchers and

1 other relevant individuals to improve the manage-
2 ment and mitigation of safety and security risks in
3 the conduct of research involving such biological
4 agents.

5 (b) REQUIREMENTS.—As a condition of receiving a
6 grant under this section, a regional biocontainment labora-
7 tory shall agree—

8 (1) to such oversight activities as the Secretary
9 determines appropriate, including periodic meetings
10 with relevant officials of the Department of Health
11 and Human Services, facility inspections, and other
12 activities as necessary and appropriate to ensure
13 compliance with the terms and conditions of such
14 award; and

15 (2) to report accidents, near-accidents, or other
16 safety incidents involving biological agents and tox-
17 ins into the no-fault reporting system established
18 pursuant to section 351B of the Public Health Serv-
19 ice Act, as added by section 402.

20 (c) DEFINITION.—In this section, the term “regional
21 biocontainment laboratory” means a Biosafety or Animal
22 Biosafety Level-3 or Level-2 facility located at an institu-
23 tion in the United States that is designated by the Sec-
24 retary to carry out the activities described in subsection
25 (a).

1 (d) AUTHORIZATION OF APPROPRIATIONS.—

2 (1) IN GENERAL.—To carry out this section,
3 there are authorized to be appropriated
4 **【\$52,000,000】** for each of fiscal years 2024 through
5 2028.

6 (2) ALLOCATION OF FUNDS.—Of the amount
7 appropriated under paragraph (1) for a fiscal year,
8 the Secretary shall allot to each regional biocontain-
9 ment laboratory receiving a grant under subsection
10 (a) for such fiscal year—

11 (A) \$1,000,000; and

12 (B) if any amount remains after allocating
13 amounts under subparagraph (A), such addi-
14 tional amounts as the Secretary may determine
15 and award to laboratories on a competitive
16 basis.

17 (e) REPORT TO CONGRESS.—Not later than 1 year
18 after the date of the enactment of this Act, and annually
19 thereafter, the Secretary, in consultation with the heads
20 of applicable Federal departments and agencies shall re-
21 port to the Committee on Health, Education, Labor, and
22 Pensions of the Senate and the Committee on Energy and
23 Commerce of the House of Representatives on—

24 (1) the activities and accomplishments of the
25 regional biocontainment laboratories;

1 (2) any published or disseminated research
2 findings based on research conducted in such labora-
3 tories in the applicable year;

4 (3) oversight activities carried out by the Sec-
5 retary pursuant to subsection (b);

6 (4) activities undertaken by the Secretary to
7 take into consideration the capacity and capabilities
8 of the network of regional biocontainment labora-
9 tories in activities to prepare for and respond to bio-
10 logical agents, which may include leveraging such ca-
11 pacity and capabilities to support the Laboratory
12 Response Network, as applicable and appropriate;

13 (5) plans for the maintenance and sustainment
14 of federally-funded activities conducted at the re-
15 gional biocontainment laboratories, consistent with
16 the strategy required under section 2312 of the
17 PREVENT Pandemics Act (Public Law 117–328);
18 and

19 (6) activities undertaken by the Secretary to co-
20 ordinate with applicable agencies to ensure work car-
21 ried out by such facilities is prioritized and com-
22 plementary to one another, and avoiding unneces-
23 sary duplication.

1 **TITLE V—ADDITIONAL REAU-**
2 **THORIZATIONS AND TECH-**
3 **NICAL AMENDMENTS**

4 **SEC. 501. EPIDEMIC INTELLIGENCE SERVICE LOAN REPAY-**
5 **MENT PROGRAM.**

6 Section 317F(c)(2) of the Public Health Service Act
7 (42 U.S.C. 247b-7(c)(2)) is amended by striking
8 “\$1,000,000 for each of fiscal years 2019 through 2023”
9 and inserting “**【\$1,000,000】** for each of fiscal years 2024
10 through 2028”.

11 **SEC. 502. TEMPORARY REASSIGNMENT OF STATE AND**
12 **LOCAL PERSONNEL DURING A PUBLIC**
13 **HEALTH EMERGENCY.**

14 Section 319(e)(8) of the Public Health Service Act
15 (42 U.S.C. 247d(e)(8)) is amended by striking “2023”
16 and inserting “2028”.

17 **SEC. 503. VACCINE TRACKING AND DISTRIBUTION.**

18 Section 319A(e) of the Public Health Service Act (42
19 U.S.C. 247d-1(e)) is amended by striking “\$30,800,000
20 for each of fiscal years 2019 through 2023” and inserting
21 “**【\$30,800,000】** for each of fiscal years 2024 through
22 2028”.

1 **SEC. 504. REGIONAL HEALTH CARE EMERGENCY PRE-**
2 **PAREDNESS AND RESPONSE SYSTEMS.**

3 Section 319C–3(e)(2) of the Public Health Service
4 Act (42 U.S.C. 247d–3c(e)(2)) is amended by striking
5 “2023” and inserting “2028”.

6 **SEC. 505. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**
7 **TION OF VOLUNTEER HEALTH PROFES-**
8 **SIONAL.**

9 Section 319I(k) of the Public Health Service Act (42
10 U.S.C. 247d–7b(k)) is amended by striking “\$5,000,000
11 for each of fiscal years 2019 through 2023” and inserting
12 “**[\$5,000,000]** for each of fiscal years 2024 through
13 2028”.

14 **SEC. 506. LIMITED ANTITRUST EXEMPTION.**

15 Section 319L–1(b) of the Public Health Service Act
16 (42 U.S.C. 247d–7f(b)) is amended by striking “at the
17 end of the 17-year period that begins on the date of enact-
18 ment of this Act” and inserting “on September 30, 2028”.

19 **SEC. 507. TRAUMA CARE.**

20 Section 1232(a) of the Public Health Service Act (42
21 U.S.C. 300d–32(a)) is amended by striking “\$24,000,000
22 for each of fiscal years 2023 through 2027” and inserting
23 **["\$24,000,000 for each of fiscal years 2024 through**
24 **2028"]**.

1 **SEC. 508. MILITARY AND CIVILIAN PARTNERSHIP FOR**
2 **TRAUMA READINESS.**

3 Section 1291(g) of the Public Health Service Act (42
4 U.S.C. 300d–91(g)) is amended by striking “\$11,500,000
5 for each of fiscal years 2019 through 2023” and inserting
6 “**[\$11,500,000]** for each of fiscal years 2024 through
7 2028”.

8 **SEC. 509. NATIONAL DISASTER MEDICAL SYSTEM.**

9 Section 2812(g) of the Public Health Service Act (42
10 U.S.C. 300hh–11(g)) is amended by striking
11 “\$57,400,000 for each of fiscal years 2019 through 2023”
12 and inserting “**[\$57,400,000]** for each of fiscal years
13 2024 through 2028”.

14 **SEC. 510. VOLUNTEER MEDICAL RESERVE CORPS.**

15 Section 2813(i) of the Public Health Service Act (42
16 U.S.C. 300hh–15(i)) is amended by striking “\$11,200,000
17 for each of fiscal years 2019 through 2023” and inserting
18 “**[\$11,200,000]** for each of fiscal years 2024 through
19 2028”.

20 **SEC. 511. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.**

21 Section 2821(b) of the Public Health Service Act (42
22 U.S.C. 300hh–31(b)) is amended, in the matter preceding
23 paragraph (1), by striking “\$190,000,000 for each of fis-
24 cal years 2019 through 2023” and inserting
25 “**[\$190,000,000]** for each of fiscal years 2024 through
26 2028”.

1 **SEC. 512. VETERANS AFFAIRS.**

2 Section 8117(g) of title 38, United States Code is
3 amended by striking “\$155,300,000 for each of fiscal
4 years 2019 through 2023” and inserting
5 “**[\$155,300,000]** for each of fiscal years 2024 through
6 2028”.

7 **SEC. 513. TECHNICAL AMENDMENTS.**

8 (a) VACCINES.—Title XXI of the Public Health Serv-
9 ice Act (42 U.S.C. 300aa–1 et seq.) is amended—

10 (1) in section 2105(b), by striking “, 2103, and
11 2104” each place it appears and inserting “and
12 2103”;

13 (2) in section 2110(b), by striking “the pro-
14 gram” and inserting “The Program”;

15 (3) in section 2111(a)—

16 (A) in paragraph (6), by striking “1988
17 for” and inserting “1988, for”; and

18 (B) in paragraph (10), by striking “United
19 States Claims Court” and inserting “United
20 States Court of Federal Claims”;

21 (4) in section 2112—

22 (A) in subsection (c)(6)(A), by striking
23 “United States Claims Courts” and inserting
24 “United States Court of Federal Claims”; and

25 (B) in subsection (f)—

1 (i) by striking “United States Claims
2 Court on” and inserting “United States
3 Court of Federal Claims on”; and

4 (ii) by striking “United States Claims
5 Court’s judgment” and inserting “judg-
6 ment of the United States Court of Fed-
7 eral Claims”;

8 (5) in section 2115(b)(3), by striking “sub-
9 section (e)” and inserting “subsection (e)”;

10 (6) in section 2117—

11 (A) in the section heading, by striking
12 “**SUBROGRATION**” and inserting “**SUBROGA-
13 TION**”; and

14 (B) in subsection (a), by striking
15 “subrograted” and inserting “subrogated”; and

16 (7) in section 2127—

17 (A) in subsection (b)(1), by inserting “and
18 Prevention” before the period; and

19 (B) in subsection (c), by striking “Com-
20 mittee on Labor and Human Resources” and
21 inserting “Committee on Health, Education,
22 Labor, and Pensions”.

23 (b) PREP AMENDMENTS.—Section 319F–3 of the
24 Public Health Service Act (42 U.S.C. 247d–6d) is amend-
25 ed—

1 (1) in subsection (c)(5)(B)(ii)(I), by striking
2 “chapter 5” and inserting “chapter V”; and

3 (2) in subsection (i)(7)—

4 (A) by striking “321(g)(1))” and inserting
5 “321(g)(1))”; and

6 (B) by striking “321(h))” and inserting
7 “321(h))”.

8 (c) COVERED COUNTERMEASURE PROCESS.—Section
9 319F–4 of the Public Health Service Act (42 U.S.C.
10 247d–6e) is amended—

11 (1) in subsection (b)(1), by striking “under
12 319F–3(b)” and inserting “under section 319F–
13 3(b)”; and

14 (2) in subsection (d)(5), by striking “under
15 subsection (a) the Secretary determines that a cov-
16 ered individual qualifies for compensation” and in-
17 serting “a covered individual is determined under
18 subsection (a) to be eligible for compensation under
19 this section”.

20 (d) SMALLPOX EMERGENCY PERSONNEL PROTEC-
21 TION.—Part C of title II of the Public Health Service Act
22 (42 U.S.C. 239 et seq.) is amended—

23 (1) in section 261(a)(2)(A), by striking “speci-
24 alities” and inserting “specialties”;

1 (2) in section 265(c)(5), by striking “involves”
2 and inserting “involved”;

3 (3) in section 266(b)(3)(B)(ii), by striking “to
4 with respect to an eligible” and inserting “with re-
5 spect to an eligible”; and

6 (4) in section 267(b), by striking “such Act”
7 and inserting “such part”.

8 (e) OTHER AMENDMENT.—Section 351A(e)(7)(B)(ii)
9 is amended by striking “judical” and inserting “judicial”.

10 **TITLE VI—ADDITIONAL POLI-**
11 **CIES OUTSIDE THE STAFF**
12 **AGREEMENT FOR STAKE-**
13 **HOLDER FEEDBACK**
14 **Subtitle A—Chair Sanders Staff**
15 **Proposal**

16 **SEC. 601. BARDA REASONABLE PRICING REQUIREMENTS.**

17 Section 319L(c)(5) of the Public Health Service Act
18 (42 U.S.C. 247d–7e(c)(5)) is amended by adding at the
19 end the following:

20 “(I) REASONABLE PRICING.—

21 “(i) IN GENERAL.—In awarding con-
22 tracts, grants, and cooperative agreements,
23 and in entering into licenses or other
24 transactions, under this section, the Sec-
25 retary shall include terms and conditions

1 requiring that the price of a qualified
2 countermeasure, qualified pandemic or epi-
3 demic product, security countermeasure, or
4 related technology developed with support
5 under this section is fair and reasonable
6 for purposes of procurement by the Fed-
7 eral Government or if sold on the commer-
8 cial market, taking into account the fol-
9 lowing factors:

10 “(I) The value of the counter-
11 measure, product, or technology to the
12 public health, including the impact of
13 the price on access to the counter-
14 measure, product, or technology.

15 “(II) The costs incurred by the
16 Federal Government in research and
17 development of the countermeasure,
18 product, or technology.

19 “(III) The costs incurred by the
20 person in research and development of
21 the countermeasure, product, or tech-
22 nology, and the costs of manufac-
23 turing such countermeasure, product,
24 or technology.

1 “(IV) Whether the counter-
2 measure, product, or technology pro-
3 vided a significant improvement in
4 health outcomes, compared to other
5 therapies available at the time of its
6 approval or authorization.

7 “(V) The cumulative expected
8 global revenues generated by the
9 countermeasure, product, or tech-
10 nology.

11 “(VI) Other factors, as the Sec-
12 retary determines appropriate.

13 “(ii) MOST FAVORED NATION.—The
14 Secretary shall include in any contract,
15 grant, cooperative agreement, license, or
16 other transaction under this section terms
17 and conditions requiring that the price of
18 a qualified countermeasure, qualified pan-
19 demic or epidemic product, security coun-
20 termeasure, or related technology devel-
21 oped with support under this section and
22 sold to the Federal Government or on the
23 commercial market not exceed the lowest
24 price charged for such countermeasure,
25 product, or technology, among Canada,

1 France, Germany, Italy, Japan, and the
2 United Kingdom.”.

3 **SEC. 602. CDC REASONABLE PRICING REQUIREMENTS.**

4 Section 305 of the Public Health Service Act (42
5 U.S.C. 242c) is amended by adding at the end the fol-
6 lowing:

7 “(f) REASONABLE PRICING.—

8 “(1) IN GENERAL.—In awarding contracts,
9 grants, and cooperative agreements, and in entering
10 into licenses or other transactions, related to the re-
11 search and development of a covered product, the
12 Director shall include terms and conditions requiring
13 that the price of a covered product developed with
14 support from the Centers for Disease Control and
15 Prevention is fair and reasonable for purposes of
16 procurement by the Federal Government or if sold
17 on the commercial market, taking into account the
18 following factors:

19 “(A) The value of the covered product to
20 the public health, including the impact of the
21 price on access to the covered product.

22 “(B) The costs incurred by the Federal
23 Government in research and development of the
24 covered product.

1 “(C) The costs incurred by the person in
2 research and development of the covered prod-
3 uct, and the costs of manufacturing such cov-
4 ered product.

5 “(D) Whether the covered product pro-
6 vided a significant improvement in health out-
7 comes, compared to other therapies available at
8 the time of its approval or authorization.

9 “(E) The cumulative expected global reve-
10 nues generated by the covered product.

11 “(F) Other factors, as the Secretary deter-
12 mines appropriate.

13 “(2) MOST FAVORED NATION.—The Director
14 shall include in any contract, grant, cooperative
15 agreement, license, or other transaction terms and
16 conditions requiring that the price of a covered prod-
17 uct developed with support from the Centers for Dis-
18 ease Control and Prevention and sold to the Federal
19 Government or on the commercial market not exceed
20 the lowest price charged for such covered product,
21 among Canada, France, Germany, Italy, Japan, and
22 the United Kingdom.

23 “(3) DEFINITION.—For the purposes of this
24 section, the term ‘covered product’ means—

1 “(A) a biological product (as defined in
2 section 351(i));

3 “(B) a drug (as defined in section
4 201(g)(1) of the Federal Food, Drug, and Cos-
5 metic Act);

6 “(C) a device (as defined in section
7 201(h)(1) of such Act); or

8 “(D) another biomedical technology.”.

9 **Subtitle B—Ranking Member**
10 **Cassidy Staff Proposal**

11 **SEC. 611. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
12 **FOR AGENTS THAT PRESENT NATIONAL SE-**
13 **CURITY THREATS.**

14 Section 565A of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 360bbb–4a) is amended—

16 (1) in subsection (a)—

17 (A) in paragraph (3)—

18 (i) by inserting “under subsection (b)
19 or (c)” after “Secretary”; and

20 (ii) by inserting “or military” after
21 “material threat” each place such term ap-
22 pears; and

23 (B) in paragraph (4)—

24 (i) in the paragraph heading, by in-
25 serting “OR MILITARY” after “THREAT”;

1 (ii) in the matter preceding subpara-
2 graph (A), by inserting “or military” after
3 “threat”;

4 (iii) in subparagraph (A)—

5 (I) in clause (i), by striking “;
6 or” and inserting a semicolon;

7 (II) by redesignating clause (ii)
8 as clause (iii);

9 (III) by inserting after clause (i)
10 the following:

11 “(ii) to prevent or treat harm from a
12 biological, chemical, radiological, or nuclear
13 agent that is determined by the Secretary
14 of Defense to present a material threat
15 against the Armed Forces sufficient to af-
16 fect national security, other than any such
17 agent that is identified as a material threat
18 to the United States population as de-
19 scribed in clause (i); or”;

20 (IV) in clause (iii), as so redesi-
21 gnated, by striking “such agent;” and
22 inserting “an agent described in
23 clause (i) or (ii);”;

24 (2) in subsection (b)—

1 (A) in the subsection heading, by inserting
2 “TRANSFERABLE” before “PRIORITY”;

3 (B) by inserting “or military” after “mate-
4 rial threat” each place such term appears; and

5 (C) in paragraph (2)—

6 (i) in the first sentence, by striking
7 “this section” and inserting “this sub-
8 section”; and

9 (ii) in the second sentence, by insert-
10 ing “awarded under this subsection” after
11 “review voucher”;

12 (3) by redesignating subsections (e) through (g)
13 as subsections (d) through (h), respectively;

14 (4) by inserting after subsection (b) the fol-
15 lowing:

16 “(c) NON-TRANSFERABLE PRIORITY REVIEW
17 VOUCHER.—

18 “(1) IN GENERAL.—In addition to the voucher
19 awarded under subsection (b), the Secretary shall
20 award another priority review voucher to the sponsor
21 of a material threat or military medical counter-
22 measure application upon approval by the Secretary
23 of such material threat or military medical counter-
24 measure application.

1 “(2) TRANSFERABILITY.—The sponsor of a ma-
2 terial threat or military medical countermeasure ap-
3 plication that receives a priority review voucher
4 under this subsection may not transfer such voucher
5 to any other person. Such a priority review voucher
6 may only be used by the sponsor to whom the vouch-
7 er is awarded.

8 “(3) NOTIFICATION.—The sponsor of a human
9 drug application shall notify the Secretary not later
10 than 90 calendar days prior to submission of the
11 human drug application that is the subject of a pri-
12 ority review voucher of an intent to submit the
13 human drug application, including the date on which
14 the sponsor intends to submit the application. Such
15 notification shall be a legally binding commitment to
16 pay for the user fee to be assessed in accordance
17 with this section.”;

18 (5) in paragraph (1) of subsection (e), as so re-
19 designated, by striking “a priority review voucher
20 under this section” and inserting “priority review
21 vouchers under subsections (b) and (c)”;

22 (6) in subsection (f), as so redesignated, by in-
23 serting “or military” after “material threat”; and

24 (7) in subsection (h), as so redesignated, by
25 striking “2023” and inserting “2028”.